In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 18-0643V UNPUBLISHED

DEBRA JUNO,

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: September 13, 2021

Special Processing Unit (SPU); Findings of Fact; Onset; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Bridget Candace McCullough, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Debra A. Filteau Begley, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On May 7, 2018, Debra Juno filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered to her right shoulder on October 10, 2016. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons discussed below, I find the onset of Petitioner's shoulder injury related to vaccine administration ("SIRVA") occurred within 48 hours of vaccination.

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Relevant Procedural History

Ms. Juno filed her petition for compensation along with medical record exhibits on May 7, 2018. (ECF No. 1). After reviewing the records, Respondent filed a status report stating that he was amenable to engaging in settlement discussions, and requested that Petitioner provide a demand. (ECF No. 14). The parties were unable to resolve the case after more than a year of settlement discussions, however, so I ordered Respondent to file the Rule 4(c) Report to identify the area of disagreement. (ECF Nos. 36, 37).

Respondent did so on February 2, 2020, maintaining therein that the case was not appropriate for compensation under the terms of the Vaccine Act. Respondent's Report at 1 (ECF No. 38). Respondent argued that "petitioner's records do not establish that her shoulder pain began within 48 hours of vaccination, and when she first sought treatment three weeks after vaccination, she actually reported bilateral shoulder pain." *Id.* at 6. Respondent further argued that Petitioner does not allege in the alternative that her shoulder pain was caused-in-fact by the vaccination, and thus, cannot prove a causal link between the alleged injuries and a covered vaccine. *Id.* at 7-8.

Petitioner filed a motion for a fact ruling ("Br.") to resolve the onset issue. (ECF No. 43). Respondent filed his response ("Opp.") on July 13, 2020. (ECF No. 44). Petitioner filed a reply ("Reply") on July 27, 2020. (ECF. No. 45). The matter is now ripe for adjudication.

II. Issue

At issue is whether the onset of Petitioner's right shoulder pain occurred within 48 hours after vaccination, as required by the Vaccine Injury Table. 42 C.F.R. §§ 100.3(a) XIV.B. (2017) (influenza vaccination) and 100.3(c)(10).

III. Authority

Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). However, the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." § 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); see also Burns v. Sec'y of

Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Parties' Positions

a. Petitioner's Arguments

Petitioner asserts that her right shoulder pain started within 48 hours of vaccination. Br. at 6-7. She notes that there are no complaints of shoulder pain prior to vaccination, and that in all her post-injury medical records she continuously related her right shoulder pain back to the flu vaccination. *Id.* at 7. In particular, just three weeks after vaccination, Ms. Juno specifically complained to her primary care physician about the pain in her shoulder "since" receiving the vaccinations on October 10, 2016. *Id.* And in all subsequent records that mention onset, Petitioner continued to relate her right shoulder pain back to her flu vaccination. *Id.* Petitioner also argues that the medical records are supported by her sworn testimony and the testimony of her fact witnesses. *Id.* at 8.

b. Respondent's Arguments

Respondent, on the other hand, argues that the 48-hour onset is only described in Petitioner's own statement and not corroborated by any objective evidence. Opp. at 4. Respondent states that Petitioner "cannot overcome inconsistencies or discrepancies in the medical records by simply filing Affidavits that state her preferred onset date." *Id.* at 8. Respondent notes that in Petitioner's initial visit to her PCP, she complained of *bilateral* arm pain, and because the record does not specifically state "right" shoulder when referring to the arm pain, such an inference cannot be made. Respondent also argues that the term "worsening" can also relate to an onset of shoulder pain prior to vaccination. *Id.* Finally, Respondent states that the Dearborn disability documents filed by Petitioner which report an onset of shoulder symptoms within 48-hours of vaccination do not substantiate her claim. Therefore, Petitioner's SIRVA claim should be denied.

V. Finding of Fact

I make the following findings after a complete review of the record to include all medical records, affidavits, Respondent's Rule 4(c) report, the parties' briefing and any additional evidence filed. Specifically, I base the findings on the following evidence:

- Ms. Juno's past medical history is significant for hypothyroidism, restless leg syndrome, gastric reflux, and a hiatal hernia. Petitioner's Exhibit ("Ex.") 2 at 2.
 She also reported a remote history of elbow surgery. Ex. 4 at 36.
- Approximately 10 days prior to receiving the vaccination at issue, on September 27, 2016, Ms. Juno was seen by her primary care provider ("PCP"), Dr. Elham Siddiqui, for an annual exam. She reported "no current complaints," and her exam was normal. There is no history of shoulder complaints noted. Ex. 2 at 22-24.
- Ms. Juno was 60 years old when she was administered a flu vaccine in her right shoulder on October 10, 2016, by a nurse at her PCP's office. Ex. 1 at 1; Ex. 7 at 8. Ms. Juno also received the Pneumovax 23 vaccine in her left deltoid during this visit. *Id*.
- In her affidavit, Ms. Juno recalled that "[i]mmediately following the influenza vaccination, I began to develop pain in my right shoulder." Ex. 10 at 1, ¶2. She stated that the nurse administering the vaccination was standing, while Ms. Juno was seated. Ex. 11 at 1, ¶3.
- Ms. Juno stated in her affidavit that she was advised by her PCP's office to wait a
 week to see if her shoulder pain subsided. *Id*. at ¶ 6. When the pain did not
 subside, she contacted her PCP again and made an appointment for November
 2, 2016. *Id*. at ¶7.
- On November 2, 2016, 23 days after vaccination, Ms. Juno presented to Dr. Siddiqui complaining of "worsening arm pain since getting flu and pneumonia vaccines." Ex. 2 at 36. Dr. Siddiqui diagnosed her with bilateral arm pain and myalgia. She was prescribed a steroid taper. *Id.* at 38.
- By December 14, 2016, Ms. Juno was still experiencing pain in her right shoulder. She returned to her PCP stating that she "still [had] difficulty raising her arm, can't take shirt off", "aching, can't reach behind," "very sore to touch." Ms. Juno stated that she had tried steroid and anti-inflammatory medications to no avail. Ex. 2 at 32. On exam, she exhibited decreased range of motion of the right shoulder, tenderness, pain and decreased strength. *Id.* at 34. Dr. Siddiqui ordered an MRI. *Id.*
- On December 21, 2016, Ms. Juno underwent an MRI of her right shoulder which demonstrated a "full thickness supraspinatus tear, partial bursal sided infraspinatus tear, and moderate osteoarthritis of the acromioclavicular joint." Ex. 2 at 64.

- On January 11, 2017, Ms. Juno was examined by orthopedic surgeon, Dr. John McPhilemy, who noted that Ms. Juno "began to experience right shoulder symptoms following a flu shot she received on or about 10/10/2016. Symptoms have persisted over the past three months..." Ex. 5 at 6-7. He recommended arthroscopic surgery to repair the tears, followed by a course of physical therapy. *Id.* at 7.
- On January 20, 2017, Ms. Juno underwent a right shoulder arthroscopic shoulder repair. Ex. 3 at 9. The postoperative diagnoses included: (1) rotator cuff tear, right shoulder, (2) degenerative glenoid labrum tear, and (3) early osteoarthritis, right glenohumeral joint. *Id*.
- Five days later, on January 25, 2017, Ms. Juno was examined by Dr. McPhilemy who noted that Ms. Juno's incisions were healing and there were no signs of infection or deep vein thrombosis. Ex. 5 at 5. She was to be reexamined in one week.
- Ms. Juno had several post-operative appointments with Dr. McPhilemy on February 1, 8, and 27, 2017. See generally Ex. 3, 5.
- On March 27, 2017, nine weeks after surgery, Dr. McPhilemy noted that Ms. Juno's pain was "slowly improving" although she was not yet pain free. Ex. 3 at 3. He recommended that Ms. Juno work with a physical therapist to improve her range of motion and to prevent adhesive capsulitis. *Id*.
- By April 17, 2017, Dr. McPhilemy noted that Ms. Juno's range of motion "is improved to about 90% of normal, pain is improved and strength is about 85% of normal." Ex. 3 at 2. Dr. McPhilemy recommended that Ms. Juno continue with physical therapy for another two weeks. *Id*.
- At her May 3, 2017 appointment with Dr. McPhilemy, Ms. Juno's right shoulder had improved but she was not pain free. Ex. 3 at 1. Dr. McPhilemy confirmed that Ms. Juno still had some restriction in her right shoulder and "uncomfortable internal rotation", but all other motion was "pretty close to normal." Strength was 90% of normal. *Id*.
- Ms. Juno attended post-surgical physical therapy from March 27, 2017 to May 31, 2017. See generally Exs. 3, 4. She was discharged from physical therapy on May 31, 2017, to a home exercise program. Ex. 3 at 5.
- Ms. Juno filed a short-term disability claim with Dearborn National Disability on January 25, 2017. Ex. 12 at 10-11. Petitioner listed her injury as "torn rotator cuff"

with symptoms first manifesting on October 11, 2016, one day after vaccination. *Id.*

The record as summarized above preponderantly supports the conclusion that Petitioner experienced right shoulder pain immediately after administration of the flu vaccine on October 10, 2016. Despite Respondent's reluctance to admit that Petitioner reported her right shoulder pain just three weeks after vaccination, the records make clear that Petitioner's right shoulder pain began immediately after vaccination and within the 48 hour onset period to prove a SIRVA claim.

Thus, just 23 days after vaccination, Ms. Juno had an appointment with her PCP to specifically complain of her shoulder pain. In her affidavit, she states that she called her PCP's office more than once to complain of shoulder pain, although the phone records have not been filed into the record. But clearly Ms. Juno made at least one phone call to set the November 2, 2017 appointment – and it was within a month of the vaccine's administration.

In addition, the record from that first appointment with Dr. Siddiqui states that Ms. Juno complained of "worsening arm pain since getting flu and pneumonia vaccines." Ex. 2 at 36 (emphasis added). This descriptor "worsening" indicates that Ms. Juno's bilateral shoulder pain started prior to the November 2, 2017 visit, and provides further evidence that her bilateral arm pain, which includes the right shoulder, was "worsening" "since" receiving the vaccinations – supporting the contention that the pain itself began at or close to the time of vaccination. Respondent's view that the term "bilateral" discounts the possibility of a Table onset is not persuasive, since Dr. Siddiqui clearly stated that Ms. Juno's arm pain stemmed from both the flu and pneumonia vaccines (and both are grounds for a Table SIRVA claim). Equally unpersuasive is Respondent's argument that bilateral pain means Petitioner could not have experienced pain in her right shoulder after receiving the flu vaccine. The medical record allows the conclusion that her left arm pain from the Pneumovax vaccine resolved (consistent with the vast majority of vaccinations), while the right arm pain lingered, and therefore *it* is the actionable vaccination.

The other factor that weighs in my finding of the 48-hour onset of right shoulder pain is the absence of any statement or record that places the onset of Ms. Juno's right shoulder pain *outside* the 48-hour window. While Respondent correctly notes in a footnote that Dr. McPhilemy's record memorialized a three-month history of arm pain - which if correct would place the onset of right shoulder pain prior to vaccination (*see* Opp. at 2, fn. 2) - it is clear that Dr. McPhilemy was generalizing the onset period, rather than precisely calculating the period for legal purposes (as is done in Vaccine Program

cases).³ Dr. McPhilemy otherwise clearly sets the onset of Petitioner's right shoulder pain as starting on 10/10/2016, and taken as a whole, this is the most reasonable interpretation of his entire statement.

Respondent further argues that Petitioner cannot overcome inconsistencies or discrepancies in the medical records simply by filing affidavits that gainsay or modify what the records set forth. But the Federal Circuit has expressly recognized that witness testimony on issues pertaining to fact matters like symptoms onset *can* be proven through this kind of evidence (even if they must be weighed against the records, which also have evidentiary significance). *Kirby*, 997 F.3d at 1383. Respondent has not otherwise identified any other inconsistencies or discrepancies in the medical records. All other references to onset clearly relate Petitioner's right shoulder pain as occurring immediately after vaccination.

Finally, Respondent questions the weight to be given affidavits filed by Petitioner in support of her claim of onset, noting in particular that Ms. Juno's second and third affidavits were written over three years after her October 10, 2016 flu vaccination, "and petitioner did not explain why she did not provide any of that information to her treating doctor's when she first sought treatment." Opp. at 3. While I accept that the date of some contentions or witness statements can be relevant to the weight they should be given, I also note that such matters are a "two-way street." Thus, as Petitioner aptly notes in her Reply brief, Respondent filed his Rule 4(c) report challenging the issue of onset on February 6, 2020 - a total of 640 days (21 months) after the Petition was filed. It was not obvious that onset would be challenged in this case, especially since Petitioner reported her shoulder injury less than 30 days after vaccination, and given that the parties did seek to settle the matter for some time.

Weighing the evidence on the preponderance standard, I overall find that Petitioner has met her burden. One of the most significant pieces of evidence is the fact that Ms. Juno was seen by her primary care physician for her right shoulder pain just 23 days after she was administered the flu vaccine. There are also many references in the medical records (as listed above) that squarely place the onset of Ms. Juno's shoulder pain in the 48-hour window. Despite Respondent's seeming view that only evidence of onset in records prepared *within* the 48-hour period set by the Table is credible, the Act says otherwise. § 13(b)(2). Taken as a whole, I find the sworn testimony of Ms. Juno to be credible and in agreement with most of the contemporaneously created treatment records.

³ The entire statement by Dr. McPhilemy states that Ms. Juno "began to experience right shoulder pain symptoms following a flu shot she received on or about 10/10/2016. Symptoms have persisted over the past three months." Ex. 5 at 6-7.

Accordingly, I find the onset of Petitioner's pain within 48 hours of vaccination.

VI. Scheduling Order

Given my finding of fact regarding the onset of Ms. Juno's right shoulder pain, Respondent should evaluate and provide his current position regarding the merits of Petitioner's case.

Accordingly, Respondent shall file, by no later than <u>Friday</u>, <u>October 15</u>, <u>2021</u>, an amended Rule 4(c) Report reflecting Respondent's position in light of the above fact-finding.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master